

REMARKS

This Amendment is filed in response to the Office Action dated November 23, 2010. Applicant has amended Claim 1. New claims 26-30 have been added. Support for the amendment and for the new claims are found in the originally filed claims, specification, drawings, and at least as described on page 4, line 18, and throughout pages 15 and 16, and in particular, page 16, lines 4 to 11, as well as page 9, lines 4 to 11. No new matter has been added.

Thus, upon entry of this amendment, Claims 1, 3, 21, and 26-30 are pending. Applicant respectfully submits that the pending claims are patentable and respectfully requests reconsideration in light of the following remarks, which follow in the order present in the Office Action (“the Action”).

Rejections under 35 U.S.C. 103(a) are Traversed

Claims 1 and 21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,895,416 (“*Barreras*”) in view of U.S. Patent No 6,516,227 (“*Meadows*”). In view of the present amendment, the rejection is traversed for at least the reasoning that *Barreras/Meadows* do not disclose or reasonably suggest all of the recited claim elements of present claim 1 or 21.

The present claims relate to an electro stimulation system for providing signals to the *skin tissue* of a subject for the purpose of *stimulating the skin tissue*. The instant claims provide a solution that is non-invasive and avoids any requirement for surgical procedures. Both *Barreras* and *Meadows* relate to solving the problem of pain relief, where the solution includes surgical implantation of probes and providing signals to those probes subsequent to the surgical operation.

Instant claim 1 recites an electro stimulation system for providing signals to skin tissue of a subject including, *inter alia*, at least three connection probes adapted for temporary external electrical connection to the skin of the subject, wherein the at least one switching control device is activated during a treatment to cause a repeatedly varying formation of probes as active probes or return probes causing the establishment of electrical currents passing through different paths

through the skin tissue of the subject. Thus, the present claim recites limitations not found in either *Barreras/Meadows*, discussed separately and then in combination below.

Barreras in the abstract discloses electric field steering assembly is used to control the size and/or location of, and/or steer the position of, an electric field “in a living creature.” Specifically, the diagrammatic representations in Figures 10, 11 and 12 of *Barreras* describes the location of surgically implantable electrodes for the control of nerve or brain response to treat intractable pain. While a range of electric fields residing between the electrodes are possible, the disclosure of *Barreras* is directed to the selection of a single electric field arrangement with ion flow (electrical current flow) passing to and from specific implanted electrodes that does not vary over time. *Barreras* is silent as to skin treatment systems and to temporary *external* electrical connections to the skin of a subject. Nor does *Barreras* suggest such a modification or provide guidance for one of ordinary skill to accomplish such a modification.

Meadows, in the abstract and claims, discloses a **spinal cord** stimulation (SCS) system. *Meadows* is silent as to skin treatment systems and to temporary *external* electrical connections to the skin of a subject. Nor does *Meadows* suggest such a modification or provide guidance for one of ordinary skill to accomplish such a modification. *Meadows* does disclose skin positioned components of its SCS system (e.g., the external trial stimulator (ETS); implanted pulse generator (IPG) battery; and recharger/circuitry), however, such components are not electrodes or functional equivalents of electrodes.

Indeed, the method and principle of operation of *Barreras* and *Meadows*, taken alone or in combination, would be frustrated by a modification from an implantable device to an external, skin treatment as to do so would modify the principle of operation of either reference by vitiating their required surgical insertion of implantable electrodes. “If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.” MPEP 2143.01(VI).

Alternatively and in addition, Applicant contends that the prior disclosures of *Barreras* and *Meadows* would not be considered analogous art to a person of ordinary skill in the art as they reside in the field of solving the problem of pain relief necessitating surgical procedures, as

both references relate to implantable electrodes *within the living subject*.

In this regard, the problem addressed by the disclosure of *Barreras/Meadows* is a distinctly different problem as compared with that of the present invention. In particular, *Barreras/Meadows* describe a method and apparatus for electrically and selectively stimulating specific nerves tissue in a living creature (See, *Barreras*, column 1, lines 8 to 9). More specifically, *Barreras/Meadows* relates to surgically implanted electrodes positioned within *in-vivo* compartments of the subject (e.g. spinal cord) which affords a more uniform and conductive environment for electrical stimulation, a property that enables *Barreras/Meadows* to target nerves. As the claims of the instant application are clearly directed to repeatedly varying electrical currents passing through different paths through the skin of a subject, the claims of the instant application and the descriptions of *Barreras/Meadows* are clearly disparate and directed to solving entirely different problems.

Thus, in contrast to the cited art, the present claims correspond to a solution to a problem that doesn't present itself in *Barreras/Meadows*, namely, problems related to uniformity of application of the electrical currents to the skin area being treated, as certain regions of skin may present a lower impedance path to the flow of electrical current and hence cause a concentration of the treatment through that region to the exclusion or limitation of other regions within the area being treated. (See, e.g., Applicant's specification at page 2, lines 23-30; page 3, lines 9-12; and page 21, line 31 through page 22, line 3). Such variation of electrical current between electrodes during a skin treatment is provided in order to provide greater uniformity of electrical current distribution through the skin tissue of a subject under treatment. Electrical stimulation of skin and that of internal, *in-vivo* tissue (e.g., nerves) would be readily distinguished by one of ordinary skill in the art as to presenting different problems and requiring different methods and devices as solutions.

Accordingly, the applicant respectfully submits that any one of ordinary skill in the art would not consider it obvious to modify the stimulation system as taught by either *Barreras/Meadows* in order to achieve the system as claimed in the instant application. In view of the proposed claim amendments and the remarks, the applicant requests favorable reconsideration of the instant claims.

New Claims 26-30 are novel and non-obvious over the art of record

New claims 26-29, which depend directly or indirectly from claim1, further recite limitations not disclosed or reasonably suggested in *Barreras/Meadows*, taken alone or in combination. For example, *Barreras/Meadows*, taken alone or in combination, do not disclose or reasonably suggest connection probes located in a pre-determined spatial relationship relative to each other for connection to the skin tissue of a subject.

Likewise, *Barreras/Meadows*, taken alone or in combination, do not disclose or reasonably suggest: attachment of the probes to a mask that is appropriately dimensioned to align the connection probes in a preferred spatial distribution across any region, or part thereof, of the skin surface of the subject; and/or that the mask is a facial mask and the pre-determined location of the probes is a preferred arrangement for connecting probes to the facial region, or part thereof, of a subject. Nor does *Barreras/Meadows*, alone or in combination, disclose or reasonably suggest the mask is a body mask and the pre-determined location of the probes is a preferred arrangement for connecting probes to a region of the body, or part thereof, of a subject.

With regard to new independent claim 30, an electro stimulation system for providing signals to the skin tissue of a subject is provided. The system claim 30 recites, *inter alia*: at least three connection probes adapted for temporary external electrical connection to the skin of the subject; wherein, during a treatment, formation of probes as active probes or return probes causes the establishment of electrical currents passing through different paths through the skin tissue of a subject. Thus, for at least the reasons set forth above, new claim 30 is novel and non-obvious over *Barreras/Meadows*.

CONCLUSION

In view of the amended claims and the remarks presented above, it is respectfully submitted that all of the present claims of the application are in condition for immediate allowance. It is therefore respectfully requested that a Notice of Allowance be issued. The Examiner is encouraged to contact Applicant's undersigned attorney to resolve any remaining issues in order to expedite examination of the present application.

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It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 13-4365.

Respectfully submitted,

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